



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/647,866 | 08/25/2003 | John S. Ng | PHA 6157.2 | 2501 |

321 7590 05/20/2004

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

BADIO, BARBARA P

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/647,866

Applicant(s)

NG ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59,60,63-66,69-82,93-101 and 141-152 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 59,60,63-66,69-82,93-101 and 141-152 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 59 and 60, drawn to a process for preparation of a 4,5-dihydro-5,7-lactone steroid compound, classified in class 540, subclass 47+.
 - II. Claim 63, drawn to a process for preparation of a compound of Formula E, classified in class 540, subclass 3+.
 - III. Claim 64, drawn to a process for preparation of a compound of Formula DE2, classified in class 540, subclass 3+.
 - IV. Claim 65, drawn to a process for preparation of a compound of Formula DE1, classified in class 540, subclass 3+.
 - V. Claim 66, drawn to a process for preparation of a compound of Formula D, classified in class 540, subclass 3+.
 - VI. Claims 69-71, drawn to a process for preparation of a compound of Formula 211, classified in class 540, subclass 47+.
 - VII. Claims 72-74, drawn to a process for preparation of a compound of Formula A211, classified in class 540, subclass 47+.
 - VIII. Claims 75-77, drawn to a process for preparation of a compound of Formula A210, classified in class 540, subclass 47+.
 - IX. Claim 78, drawn to a process for preparation of a compound of Formula A209, classified in class 540, subclass 47+.

Art Unit: 1616

- X. Claim 79, drawn to a process for preparation of a compound of Formula A205, classified in class 540, subclass 47+.
- XI. Claim 80, drawn to a process for preparation of a compound of Formula A204, classified in class 540, subclass 47+.
- XII. Claim 81, drawn to a process for preparation of a compound of Formula A204, classified in class 540, subclass 47+.
- XIII. Claim 82, drawn to a process for preparation of a compound of Formula A203, classified in class 540, subclass 47+.
- XIV. Claims 93-101, drawn to a process for preparation of an epoxy steroidal, classified in class 540, subclass 47+.
- XV. Claims 93-101, drawn to a process for preparation of an epoxy non-steroidal compound, classified in class 549, subclass 200+.
- XVI. Claim 141, drawn to a compound of Formula D, classified in class 540, subclass 47+.
- XVII. Claim 142, drawn to a compound of Formula E, classified in class 540, subclass 3+.
- XVIII. Claim 143, drawn to a compound of Formula F, classified in class 540, subclass 3+.
- XIX. Claims 144-145, drawn to a compound of Formulae 211 or 210, classified in class 540, subclass 47+.
- XX. Claim 146, drawn to a compound of Formula 209, classified in class 540, subclass 47+.

Art Unit: 1616

XXI. Claims 147-148, drawn to a compound of Formulae 208 or 207, classified in class 540, subclass 3+.

XXII. Claim 149, drawn to a compound of Formula 206, classified in class 540, subclass 3+.

XXIII. Claims 150-151, drawn to a compound of Formulae 205 or 204, classified in class 540, subclass 47+.

XXIV. Claim 152, drawn to a compound of Formula 203, classified in class 549, subclass 612+.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-XV are unrelated because they are drawn to preparation of different compounds and/or utilization of different reaction or starting material and, thus, each process has different modes of operation, different functions, and/or different.

3. Inventions I-XV are unrelated because they are drawn they are drawn to different steroidal derivatives.

4. Inventions I-XV and XVI-XXIV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different

Art Unit: 1616

process (MPEP § 806.05(f)). In the instant case the product as claimed can be made another and materially different process (see for example, Inventions XI and XII).

5. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from under the elected Group for search purposes, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1616

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

Art Unit: 1616

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

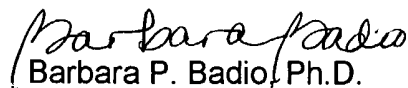
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Application/Control Number: 10/647,866

Page 8

Art Unit: 1616

you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB

May 18, 2004